



## Participant Information Sheet

*Parent/carer version*

**Title of Project: The Effect of Strength Training on Brain and Muscle Function in Children with Cerebral Palsy: A Pilot Study.**

**Researcher name: Fatema Shamsaddin**

### **Invitation and brief summary:**

*We are inviting you to take part in our study. It consists of 8-weeks home- strength training programme for children with cerebral palsy. Please take the time to discuss this with your family or GP if you wish. If you have any questions please do not hesitate to ask the researcher.*

*Thank you very much for your interest.*

### **Purpose of the research:**

*This research aims to understand the effect of strength training on muscle size and how well the muscles work, as well as muscle and brain connection and function in children with cerebral palsy.*

*Strength training is one of the commonly used therapies for children with CP. However, it is still not clearly understood how training affect the brain-muscle connection.*

*This study will help us understand how children's muscle strength and function improves in children with CP. Information will be used to optimise the current clinical practice for children with CP.*

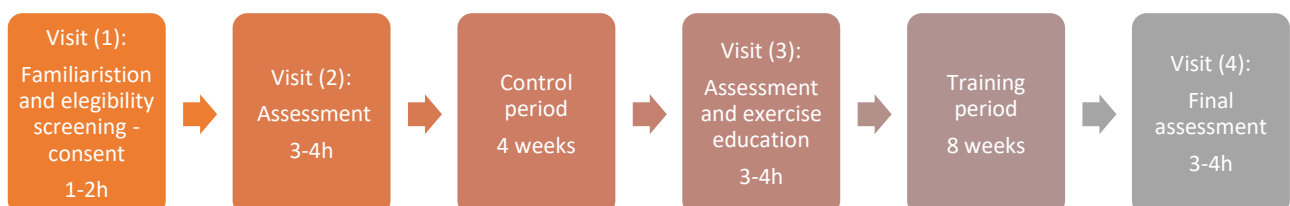
### **Why have I been approached?**

*Because we are looking to recruit children with cerebral palsy, able to walk with/without assistive device, ages between 5-14 years old.*

### **What would taking part involve?**

*Taking part involves performing the strength training exercises at home for 50 minutes per day for 3 days every week for 8 weeks. You will need to attend 4 visits at Saint Luke's campus, University of Exeter. (Please see the flow chart)*

*On the day of the visits, your child might not be able to go to school, however, we will provide a letter confirming that they are taking part in this research. If this was not acceptable by the school, please let us know and we will try to adjust to a more convenient time.*



**Visit 1:** once you arrive to St. Luke's campus, University of Exeter, you and your child will meet the researcher (Fatema Shamsaddin). Fatema will show you all the tools that will be used and check that your child can take part in the study. You can ask any questions at any time. If you and your child are willing to take part, we will ask you to sign the consent forms and book the next visit. **This session will take approximately 1-2 hours.**

**Visit 2, 3, and 4:** in each of these visits, we will make a series of measurements on your child. We will measure your child's muscle function and strength, as well as brain-muscle connection.

**The following measurements will be used to assess muscle function and strength:**

Gross Motor Function Measure (GMFM): we will ask you child to complete a series of functional tasks such as: standing, walking, running, and jumping.

6-minute walk test (6MWT): we will ask your child to walk on a treadmill for 6 minutes and we will measure the distance that you child is able to cover in that time. The speed of the treadmill will be adjusted to your child's instructions to allow them to cover their maximum distance.

Leg strength: while your child is seated and supported in a chair. We will hold a small device against your child's chin, slightly above the ankle, and will ask them to kick as strong as they can for a few seconds.

Muscle size and structure: your child will be asked to lie down on a bed, we will place some ultrasound gel and an ultrasound probe on the skin of the leg and then take pictures of the muscles above and below the knee of both legs. This will allow us to measures the muscle size and structure.

**For brain–muscle connection:**

Magnetic stimulation of the brain can be used to measure how the brain communicates with the muscle. When a magnetic pulse is delivered to the scalp over the motor cortex area, which is an area on the brain which controls and corresponds to different parts of the body, it induces a small electrical current in the nerve cells closest to the magnet. This causes a brief involuntary contraction of the muscles controlled by the stimulated area of the motor cortex. The level of muscle activation caused by the stimulation is measured using electromyography electrodes attached to the skin of the thigh, and by the measurement of the force produced.

Transcranial magnetic stimulation (TMS) – We will apply very brief magnetic stimulations to the scalp above the motor cortex. We will stimulate the area of the motor cortex linked to the thigh muscle. A gradually increasing stimulations will be delivered until the muscle twitches in response to the stimulation this is known as the motor threshold. Then your child will receive stimulations with gradually increasing intensity while contracting their leg muscle slightly.

\*The TMS assessment is an **optional** part of the study. If you would like to complete the study except for the TMS element that is fine.

The transcranial magnetic stimulation procedures could take about 1 hour, we will try to make the experience fun and engaging for your child, we can display their favourite movie, show, or they can listen to some music during the preparation and rest periods.

*Variety of snacks and drinks will be provided so you and your child can enjoy it.*

**After visit 2**, your child can go back to their normal routine, they will only be asked to wear an accelerometer during the day, which is a bracelet that measures their physical activity for 1 week.

**After visit 3**, your child will start the progressive functional strength programme, for 8 weeks, and then after 48 hours of the last training session they will come for the last assessment session.

### **What are the possible benefits of taking part?**

*Performing the exercises could help your child become stronger, and taking part in this research could help us understand better how children with CP respond to training, and the type of changes that happen in their body after training. Results of the study and a full-report of the child's motor and muscle function will be provided for each participant.*

### **What are the possible disadvantages and risks of taking part?**

Exercise: due to the nature of the exercise, your child might feel slightly tired after the training sessions. Some exercises requires using a step/bench, which could contain a risk of tripping or fall, therefore, exercises must be completed with supervision and caution.

TMS: TMS can be uncomfortable, although the brain itself does not contain nerves for feeling pain, the surrounding tissues do: blood vessels, skin, other nerves and muscles. Any of these tissues near to the coil will also be stimulated, muscles in the scalp will twitch, and your eyes may blink following stimulation too. There will be a brief click sound from the stimulation coil, which can be loud so ear plugs can be provided. If there is a nerve directly under the skin over the area of the scalp stimulated, it is possible that this will cause some pain or discomfort.

*There are no reported harmful side effects from TMS, although it may induce a headache in some susceptible individuals. These are easily treated with a mild pain killer.*

Accelerometer: in some cases, wearing the accelerometer could cause some irritation in the skin under it, if this happens, please remove and wash the area and contact the researcher to replace it.

### **How will we work safely to reduce the risk of COVID (SARS-CoV-2)?**

*All assessment tools will be cleaned and sanitised before each child arrives to make sure that children and their families are not exposed to any possible harm related to COVID.*

### **What will happen if I don't want to carry on with the study?**

*It is completely up to you if you do not want to carry on with the study, you can inform the researcher at any time without having to give a reason. You can request that your child's collected data to be removed from our records.*

### **How will my information be kept confidential?**

The University of Exeter processes personal data for the purposes of carrying out research in the public interest. The University will endeavour to be transparent about its processing of your personal data and this information sheet should provide a clear explanation of this. If you do have any queries about the University's processing of your personal data that cannot be resolved by the research team, further information may be obtained from the University's Data Protection Officer by emailing [informationgovernance@exeter.ac.uk](mailto:informationgovernance@exeter.ac.uk). Or at <http://www.exeter.ac.uk/ig/>

*Collected data will be stored in the researcher's password-protected University-owned laptop. After the study is completed you will receive a full report of all your child's assessment and the results of the study.*

**Will I receive any payment for taking part?**

*Yes, after completing the study. As an appreciation for your time and effort, you (the parent/carer) will receive £100 as a direct transfer. Your participating child will receive an Amazon shopping voucher of £100.*

*During the study period, transportation fees to the University (whether it is by train/bus/car) will be paid for all participating families, even in the cases of dropouts.*

*After each visit, a gift bag will be given to your child to encourage them to perform the exercises at home and attend assessment sessions.*

**What will happen to the results of this study?**

*The results of the study might be used for academic publication or scientific conferences. After the study is completed, you will receive an invitation to join a meeting where the full results of the study will be presented and discussed (attending is optional).*

**Who is organising and funding this study?**

The sponsor for this study is the University of Exeter.

*Research team: Fatema Shamsaddin.*

*Professor Joanna Bowtell.*

*Professor Christopher Morris.*

**Who has reviewed this study?**

This project has been reviewed by the Public Health and Sport Sciences Research Ethics Committee at the University of Exeter (Reference Number: 529822).

**Contact for any questions or requests regarding your participation in this research**

In the event of queries or requests you may contact me using the following contact information. Please email [fs382@exeter.ac.uk](mailto:fs382@exeter.ac.uk)

To contact the Research Ethics Committee

please email [ethics@exeter.ac.uk](mailto:ethics@exeter.ac.uk).

You can also contact the University Research Ethics and Governance Team if you wish to make a complaint or comment please email [cgr-reg@exeter.ac.uk](mailto:cgr-reg@exeter.ac.uk)

Thank you for your interest in this project!